

Femoral component loosening in high-flexion total knee replacement

An in vitro comparison of high-flexion *versus* conventional designs

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Abstract

High-flexion total knee replacement (TKR) designs have been introduced to improve flexion after TKR. Although the early results of such designs were promising, recent literature has raised concerns about the incidence of early loosening of the femoral component. We compared the minimum force required to cause femoral component loosening for six high-flexion and six conventional TKR designs in a laboratory experiment.

Each TKR design was implanted in a femoral bone model and placed in a loading frame in 135° of flexion. Loosening of the femoral component was induced by moving the tibial component at a constant rate of displacement while maintaining the same angle of flexion. A stereophotogrammetric system registered the relative movement between the femoral component and the underlying bone until loosening occurred.

Compared with high-flexion designs, conventional TKR designs required a significantly higher force before loosening occurred ($p < 0.001$). High-flexion designs with closed box geometry required significantly higher loosening forces than high-flexion designs with open box geometry ($p = 0.0478$). The presence of pegs further contributed to the fixation strength of components.

We conclude that high-flexion designs have a greater risk for femoral component loosening than conventional TKR designs. We believe this is attributable to the absence of femoral load sharing between the prosthetic component and the condylar bone during flexion.

Keywords: loosening, high-flexion, femoral component, in-vitro, implant design

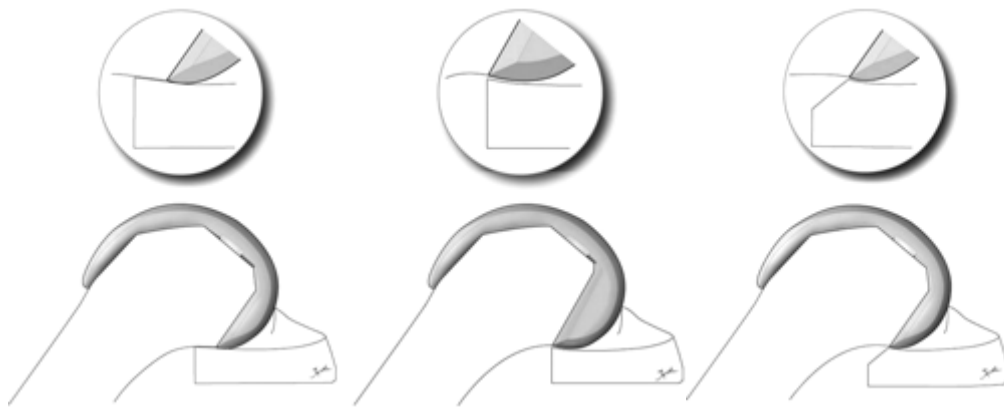
Introduction

Modern total knee replacement (TKR) generally provides satisfactory pain relief and improved knee function,¹ but patients rarely regain full flexion.² Most TKR designs enable the patient to achieve flexion of between 110° and 125°, which is significantly less than the 140° to 150° that can be achieved with a normal knee.³ Activities that require deep flexion, such as squatting, kneeling and praying, are therefore often impossible for patients after TKR.⁴ Many factors influence the range of movement that is achieved after TKR, among which are the pre-operative range, body mass index, surgical technique, prosthetic design and post-operative rehabilitation.⁵

Recently, specific so-called high-flexion TKR designs were developed in order to improve maximum flexion after TKR. Several authors have shown that an improvement in post-operative range of movement can indeed be achieved with these high-flexion designs compared with conventional TKR designs,⁶⁻⁸ although some have also not shown significant improvement.⁹⁻¹¹

Despite these results, there have been reports of early loosening of the femoral component in some high-flexion designs. Han, Kang and Yoon¹² noted a rate of aseptic loosening of the femoral component of 38% of their cases treated with one specific high-flexion design, which could be attributed to certain characteristics of the design and/or the greater degree of flexion obtained by these patients. Others have expressed concerns about the increased stress imposed on the femoral component during deep flexion activities, which could lead to loosening.^{13,14}

It was our hypothesis that certain design characteristics could contribute to the strength of femoral fixation. One of these is load sharing between the femoral component and posterior condylar bone that occurs in deep flexion when the tibial insert impinges directly against the femur (Fig. 1a). Such load sharing is influenced by the thickness of the femoral component's posterior condyles and the shape of the posterior lip of the polyethylene insert. Modern high-flexion TKR designs typically have an increased posterior condylar metal thickness and/or a posteriorly bevelled tibial insert. Together these features reduce the extent of load sharing in deep flexion. In this position, the tibial inserts of these designs are intended to articulate only with the femoral component, which in theory could cause greater shear forces on the femoral component during deep flexion (Figs 1b and 1c). For this reason we suspected that high-flexion designs might have a greater risk for loosening of the femoral component.



Figs. 1a - 1c: Drawings depicting deep flexion (135°) with a) a conventional design, b) a high-flexion design with increased posterior metal thickness, and c) a high-flexion design with a bevelled posterior edge on the polyethylene insert. Note that only in the conventional design the insert is in contact with both the femoral component and the bone.

Another design factor that could influence the strength of fixation of the femoral component is its internal geometry, which can be open, parallel or closed. We also wanted to investigate the influence of femoral pegs on the strength of fixation.

We thus investigated the influence of the external and internal geometry as well as the presence of femoral pegs on the fixation of the femoral component in six high-flexion designs, compared with six conventional TKR designs. Our hypothesis was that less force was required to loosen the femoral component in high-flexion designs than in conventional designs, and that the internal geometry of the femoral component as well as the presence of femoral fixation pegs plays a role.

Materials and Methods

A total of 12 contemporary TKR systems were analysed: six high-flexion and six conventional designs (Table I). Only posterior-stabilised components were used. The loosening force, defined as the total force required in order to loosen the femoral component, was determined for each design. Each design was tested five times under the same experimental conditions, making a total of 60 tests.

Table I: List of the total knee replacement designs used in this study, with their characteristics

Design	Prosthesis	Company*	Type	Internal femoral component geometry	Pegs	Site of design modification	Mean (sd) loosening force (N)
A	Journey	Smith &	High-flexion	Closed	No	Femoral	185 (87.3)

Design	Prosthesis	Company*	Type	Internal femoral component geometry	Pegs	Site of design modification	Mean (sd) loosening force (N)
		Nephew				component	
B	NexGen LPS-flex	Zimmer	High-flexion	Open	Yes	Femoral component	32 (17.3)
C	PFC Sigma HF	DePuy	High-flexion	Open	No	Femoral component	127 (54.5)
D	Scorpio HF	Stryker Howmedica	High-flexion	Parallel	Yes	Tibial insert	228 (65.0)
E	Genesis II HF	Smith & Nephew	High-flexion	Parallel	No	Tibial insert	148 (37.2)
F	Genesis II HF	Smith & Nephew	High-flexion	Parallel	Yes	Tibial insert	222 (18.9)
G	Genesis II	Smith & Nephew	Conventional	Parallel	No		218 (9.6)
H	Genesis II	Smith & Nephew	Conventional	Parallel	Yes		259 (11.2)
I	NexGen LPS	Zimmer	Conventional	Open	Yes		190 (28.2)
J	PFC Sigma	DePuy	Conventional	Open	No		383 (59.8)
K	Scorpio	Stryker Howmedica	Conventional	Parallel	Yes		370 (48.8)
L	Plus knee	Smith & Nephew	Conventional	Open	No		443 (95.7)

* Smith & Nephew (Memphis, Tennessee), Zimmer (Warsaw, Indiana), DePuy (Warsaw, Indiana), Stryker & Howmedica (Mahwah, New Jersey)

Test set-up

The femoral component of each design was implanted in a left femoral bone model (MITA Knee Inserts; Medical Models Ltd, Twickenham, United Kingdom) with anatomical morphology.¹⁵ The use of a standard model allowed us to eliminate the potential effect of morphological variability as well as the effect of differences within bone. In order to ensure a tight fit between the femoral component and the bone, the internal geometry of each TKR was measured with a laser scanner to enable the models to be matched with a laser cutter. This allowed precision in preparation of the bone, without surgical error. For TKR designs with

pegs, peg holes were drilled in the bone using the drill bit as recommended by the manufacturer. The femoral component was introduced according to the correct surgical technique and the bone was made flush with the implant at the posterior condyles using a rongeur. The femoral bone with the implant was then clamped in a loading frame (Flextest SE; MTS, Eden Prairie, Minnesota) in 135° of flexion with respect to the tibial insert. This angle of flexion was based on the observation of a higher incidence of loosening *in vivo* for a specific high-flexion design, with a mean pre-revision maximum flexion of 136° in a group of patients with aseptic loosening of the femoral component.¹²

The tibial insert was fixed to the vertical actuator of the loading frame, ensuring engagement of the femoral cam with the post. The post-cam mechanism served as a reproducible and accurate indicator for the relative anteroposterior positioning of the femoral and tibial components in deep flexion (135°). Several studies have confirmed that the cam engages with the post at between 40° and 100° of flexion, and remains in contact during deep flexion.¹⁶⁻¹⁹

In order to record the movement of the femoral component with respect to the femoral bone during the test, a stereophotogrammetric system was used (Vicon, Oxford, United Kingdom). A total of seven reflective markers were firmly attached to the set-up, three into the bone with 4 cm long pins, two onto the femoral component with cyanoacrylate adhesive, one on the actuator of the loading frame and one on the bottom plate of the loading frame (Fig. 2). Four infrared cameras were positioned around the loading frame for the acquisition of the markers' kinematics.

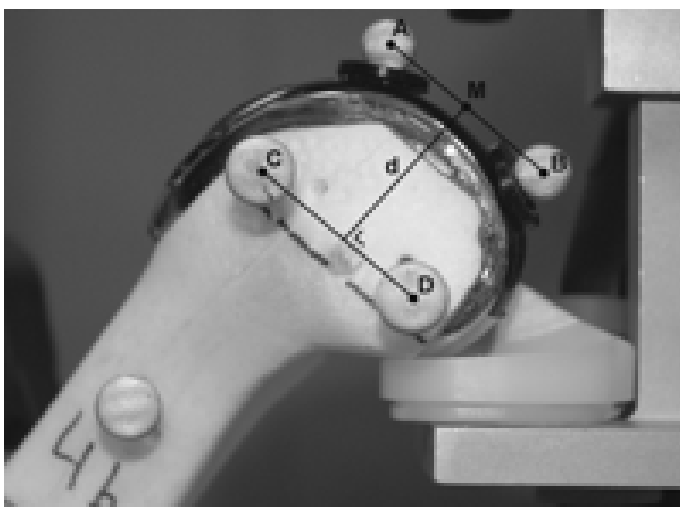


Fig. 2 : Photograph showing the test set-up with the knee model in the loading frame with the markers (A, B, C and D) attached. AB is parallel to the distal flange of the prosthesis and CD is parallel to the distal cut of the bone The line 'd' is drawn perpendicular to CD from the

midpoint (M) of AB. The change in the length of 'd' over time thereby corresponds to the relative displacement between prosthesis and bone.

Test protocol

The stereophotogrammetric system was calibrated and the origin of the global coordinate system was defined. This was done at the start of each test day, in order to ensure the same accuracy and reference coordinate system over the entire test period. After clamping the femoral bone in the loading frame, the actuator initially moved upwards until the insert and the femoral model came into contact. This was achieved when a resisting force of 10 N was measured by the loading frame, after which the actuator moved upwards at a constant vertical displacement rate for 10 seconds until a total displacement of 20 mm was achieved. During the movement, the resisting force and the displacement of the actuator were recorded continuously at a sample rate of 100 Hz using the load cell and displacement sensor of the loading frame. The stereophotogrammetric system registered the movement of the markers placed on the bone, the femoral component and the actuator.

Data analysis

Data were processed using Matlab (R2008a; The MathWorks, Natick, Massachusetts). Data from the loading frame and from the Vicon system were synchronised using the start of the actuator displacement as a common reference. The relative displacement over time between prosthesis and bone was calculated for each time frame, as shown in Figure 2: in the sagittal plane, two lines were defined by connecting the centres of the spherical markers A and B and of the markers C and D. Line AB was parallel to the distal flange of the prosthesis and line CD was parallel to the distal cut of the bone. The displacement during loosening of the femoral component is expected to be the largest in a direction perpendicular to the distal cut. Therefore, a line segment (d) was constructed starting in the midpoint (M) of line segment AB and ending on line segment CD, perpendicular to it. The change in the length of this segment over time corresponds to the relative displacement between prosthesis and bone.

The resisting force was then plotted as a function of this relative displacement. Two phases were observed in this 'force-displacement' curve: an initial linear phase with a higher slope, in which the force rises rapidly with the displacement; and a secondary stationary phase with a lower slope, in which the force is almost constant over displacement and exceeds the frictional resistance of the bone. In order to minimise errors in the measurement of the

loosening force, the force in the stationary phase was measured. Loosening was determined when a displacement of 2 mm was recorded. The corresponding force was defined as the loosening force.

Fracture of the bone model occurred in some cases, but always after a relative displacement > 2 mm. In one design ('L') the bone broke before a 2 mm displacement was reached. For this design the maximum recorded force (just before fracture) was taken as the loosening force. Obviously, this design had the highest loosening force.

The results were examined with reference to the type of prosthesis, the internal geometry of the femoral component and the presence of pegs. For each of these, the TKRs were subdivided accordingly (Table I). However, the effects of the internal geometry and the presence of pegs on the loosening force were only evaluated for the high-flexion designs. This was because a higher incidence of loosening has been found clinically for certain high-flexion designs, whereas conventional designs do not usually achieve deep flexion of 135° or more.

Prosthesis type

Deep flexion is limited mostly by direct impingement of the posterior aspect of the tibial insert against the posterior aspect of the femur.²⁰ In the high-flexion designs the curvature of the articulation in deep flexion and the posterior condylar offset of the femoral component are increased,⁶ allowing impingement-free articulation in greater degrees of flexion. Depending on the high-flexion design, this is obtained by either extending the posterior femoral condyles (Fig. 1b) or by chamfering the posterior margin of the tibial insert (Fig. 1c). Although several authors have shown that deeper flexion can be achieved with these high-flexion designs,⁶⁻⁸ this benefit is less clear when comparing high-flexion with conventional designs in posterior-stabilised TKRs,²¹ as the conventional posterior-stabilised TKRs already achieve deeper flexion than cruciate-retaining TKRs.^{22,23}

Internal geometry of the femoral component

Three different types of high-flexion design were tested, each possessing a different internal geometry for the femoral component: closed box, parallel box and open box. The angle α between the bone surface of the posterior condyles and the bone surface of the anterior flange was measured (Fig. 3) and we classified the design as closed box if $\alpha < -3^\circ$, as parallel box for $-3^\circ \leq \alpha \leq 3^\circ$, and as open box when $\alpha > 3^\circ$.

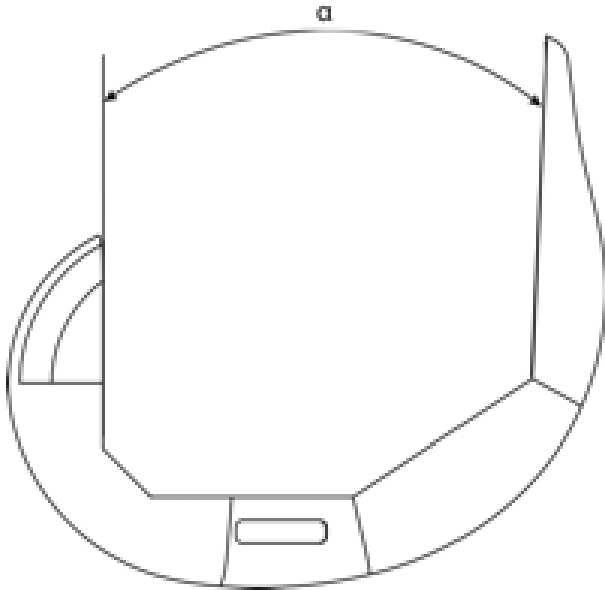


Fig. 3: Diagram defining the angle α used to classify the designs according to the internal geometry of the femoral components.

The presence of pegs

In order to evaluate the influence of pegs on fixation, the high-flexion designs were subdivided into those with and without pegs.

Statistical analysis

The mean loosening force and the standard deviation (sd) were calculated for each series of five measurements. An independent two-tailed *t*-test was used for statistical evaluation and $p < 0.05$ was considered significant in all tests.

Results

Mean loosening force

The mean (sd) loosening forces for the 12 designs are shown in Table I and Figure 4. The green bars in Figure 4 (prostheses A to F) represent the high-flexion designs and the blue bars (prostheses G to L) the conventional designs.

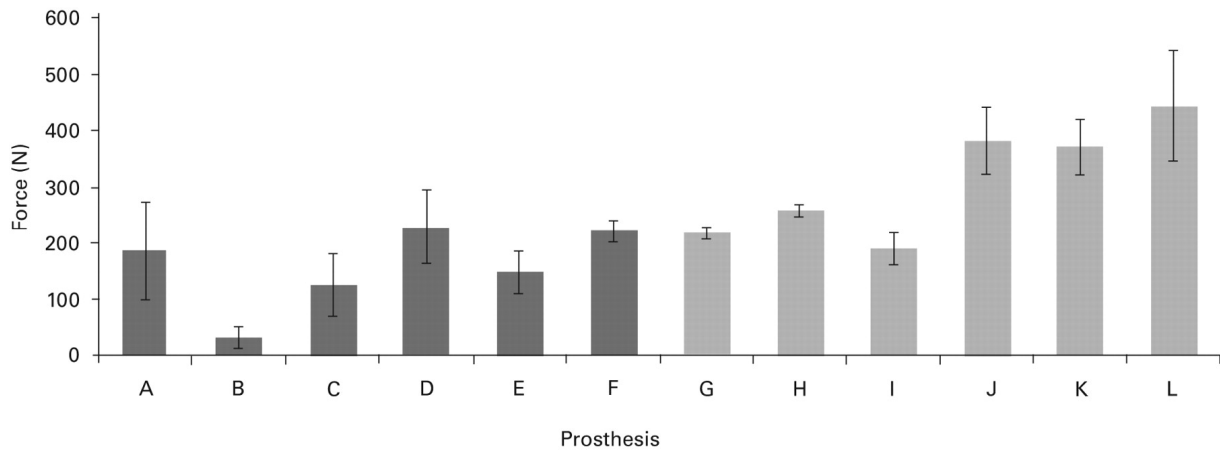


Fig. 4: Bar chart showing the mean loosening force in the 12 posterior-stabilised designs of total knee replacement tested. Error bars indicate one standard deviation away from the mean. Prostheses A to F (dark grey) are high-flexion designs, prostheses G to L (light grey) are conventional designs (Table I).

High-flexion *versus* conventional designs

The mean loosening force for the high-flexion designs was 159 N (sd 84) and for the conventional designs was 307 N (sd 108) (Fig. 5); thus, conventional designs required a significantly higher force before loosening occurred than did high-flexion designs ($p < 0.001$).

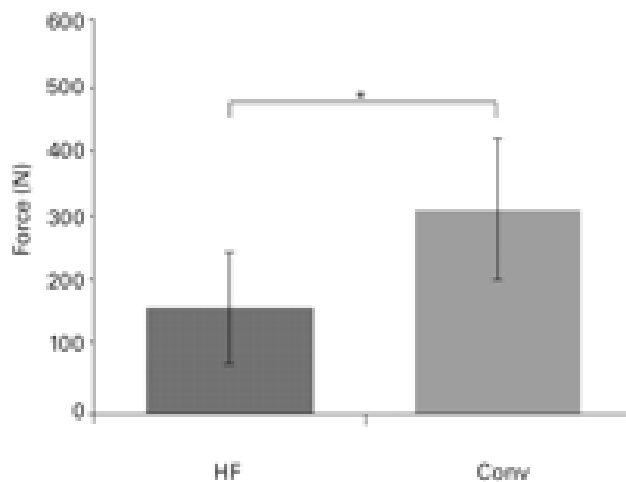


Fig. 5: Bar chart showing the mean loosening force in high-flexion (HF) *versus* conventional (Conv) designs of total knee replacement (* $p < 0.001$). Error bars indicate one standard deviation away from the mean.

The geometry of the internal box of the femoral component

The mean loosening forces for high-flexion TKR designs with a closed box, a parallel box and an open box design are shown in Figure 6. There was a statistically significant difference between the parallel and the open box designs ($p < 0.001$) and between the closed and the

open box designs ($p = 0.048$). There was no significant difference between the closed box and the parallel box designs ($p = 0.776$).

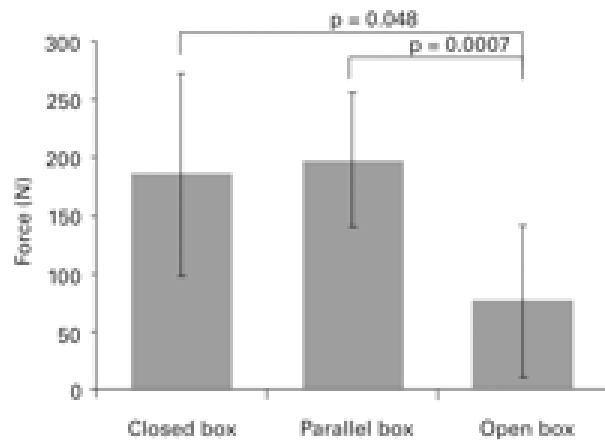


Fig. 6: Bar chart showing the mean loosening force for high-flexion total knee replacements with closed box, parallel box and open box designs. Error bars indicate one standard deviation away from the mean.

The presence of pegs

The influence of pegs on the loosening force for different designs is shown in Figure 7. The Genesis II HF and Genesis II designs (Smith & Nephew, Memphis, Tennessee) permit removal of the pegs by unscrewing them from the femoral component. A comparison of these implants without pegs and with pegs demonstrated a significant decrease in loosening force in the absence of the pegs ($p = 0.009$ for Genesis II HF and $p = 0.0006$ for Genesis II). The effect of the pegs was further evaluated for Genesis II HF by over-drilling the peg holes in the bone so that the pegs were loose in the holes. In this situation the loosening force fell significantly ($p = 0.0007$) to the same level as the loosening force without pegs, indicating the importance of good fixation of the pegs in the holes.

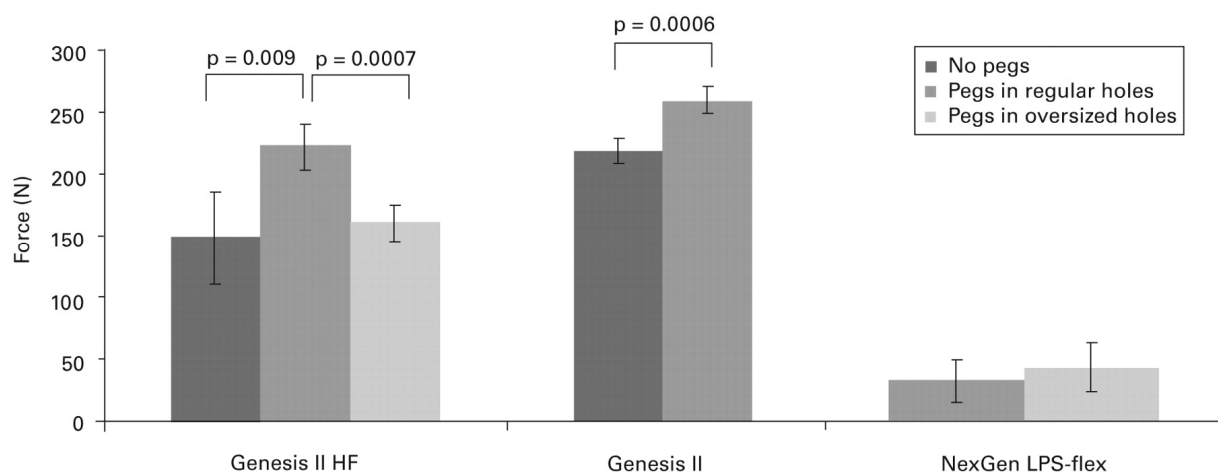


Fig. 7: Bar chart showing the influence of pegs on the mean loosening force for the Genesis II HF, Genesis II and NexGen LPS-flex designs. Error bars indicate one standard deviation away from the mean.

The NexGen LPS-flex (Zimmer, Warsaw, Indiana) design is only available with pegs attached, so the situation without pegs could not be tested. When comparing the loosening force of this design with pegs in tight-fitting holes and with pegs in oversized holes, no statistically significant difference was found ($p = 0.07$). This indicates that in this design the pegs do not contribute to fixation.

Discussion

The literature on the influence of design on the loosening of implants is limited. However, together with the cementing technique,²⁴⁻²⁶ the design and fit of the components are potentially important factors determining the strength and durability of fixation.^{27,28}

High-flexion TKR designs were introduced in an attempt to provide greater flexion, with modifications to prevent impingement of the posterior tibial articular surface against the bone and to increase the articulating surface of the posterior femoral condyle during deep flexion.^{6,20,29,30} Depending on the type of high-flexion design (Table I), such modification can involve the femoral component by increased excursion of the posterior condylar metal (Fig. 1b), or the tibial insert by a more bevelled posterior edge of the insert (Fig. 1c). In either case, in theory, the insert will not impinge on the posterior femur in flexion, thereby enabling a greater range of movement. However, this results in the tibial insert of a high-flexion TKR having contact only with the femoral component during deep flexion. In contrast, in a conventional design (Fig. 1a) the insert makes contact with both the femoral component and the femoral bone, thereby transferring lower forces to the femoral component in deep flexion than in the high-flexion designs, where no load sharing occurs. The absence of this load sharing during flexion might lead to a higher loosening rate for high-flexion TKRs.

Our investigation showed a statistically significant difference in loosening forces between high-flexion and conventional designs (Fig. 5), with a force almost twice as high required to cause loosening in the conventional knees as in the high-flexion designs.

Consideration of the internal geometry of the femoral component alone demonstrated that the internal box geometry had a statistically significant effect on the fixation strength of the high-

flexion femoral component (Fig. 6), with open box high-flexion designs having significantly lower loosening forces than closed and parallel box high-flexion designs.

In conventional designs no significant difference was found between open and parallel internal geometries and the mean loosening forces ($p = 0.40$), presumably owing to the importance of load sharing described above.

Our study revealed that fixation pegs increase the intrinsic stability of the femoral component. The presence of pegs in the Genesis II and Genesis II HF designs significantly increased the resistance against loosening (Fig. 7). In contrast, the presence of pegs in the NexGen LPS-flex design did not provide the same effect. This might be explained by the use of smooth and conical pegs in the NexGen design, whereas other designs have cylindrical pegs with grooves or fins, which increase the resistance to movement by increasing the contact area between the peg and the bone. In all designs with pegs, the diameter of the drill bit for the peg holes was smaller than the peg diameter, so that some press-fitting always occurred.

These findings may explain why some of the newer high-flexion designs have been associated with increased early loosening rates. Early clinical studies of high-flexion designs have shown that they can lead to an excellent clinical outcome, with kinematic patterns similar to those of healthy knees.²⁹ However, Han et al¹² reported an unacceptably high rate of loosening of the femoral component of the NexGen LPS-flex design, with failure at the implant-cement interface. This specific design has an increased implant thickness at the posterior condyles which prevents load sharing with the bone in deep flexion, but also has an open internal box geometry and non-functional pegs.

We recognise the limitations of this study. Despite the fact that we used a standard and reproducible model, the tests were performed without cement, which does not reflect the situation *in vivo*, where additional strength is provided either by a cement layer or by bone ingrowth. Our data should therefore be interpreted with caution. However, our purpose was not to measure and compare the absolute strength of fixation of different femoral components, but rather to determine their inherent stability, based purely on their geometrical features.

Nevertheless, we strongly believe that this inherent stability is also clinically relevant. First, it has recently been shown that the strength of fixation of a cement layer reduces dramatically, beginning within two weeks of implantation.³¹ Thus, even in cemented implants the inherent

stability of the components might be more important than is often assumed. Secondly, the cement layer created during surgery, particularly in the posterior cuts, is not always optimal.²⁶ Also, in these situations these results could shed some light on the possible increased risk of loosening with some devices.

Furthermore, we believe that cementing the implants would have introduced additional variability in the strength of fixation because of less controllable parameters such as differences in the amount of cement used and its depth of penetration into the bone. Recently, cementing technique of the femoral component has been shown to affect the occurrence of radiolucent lines, and thus the risk of loosening of the femoral component.²⁵ The femoral component is held in place during deep flexion by a combination of compressive and frictional forces, mainly acting on the posterior cut and, to a lesser extent, on the distal cut. Although cement can add some tensile strength to the interface by virtue of its interlocking with the porosity of the bone, this increase in tensile strength is limited, as the overall strength of the entire bone-cement-implant interface is determined by the weakest link, which will be at the cement-implant surface where little interdigitation will be present. Recent literature has shown that the strength of the bone-cement interface is greatly reduced after only two weeks *in vivo*, perhaps owing to remodelling of bone.³¹ The presence of cement therefore does not change the nature of the force system, but rather increases the value of the friction forces. As such, our results without cement do provide an indication as to the ranking of the femoral components according to stability, which is likely to be applicable with cement.

Another limitation of this study is the fact that this is a basic biomechanical *in vitro* study, which cannot recreate the parameters that affect the loading of the knee and the strength of fixation *in vivo*, such as patellofemoral contact, thigh-calf contact,³² soft tissues surrounding the joint, body weight, the patient's lifestyle, and the use of a cemented *versus* a cementless design. Therefore, the absolute values obtained for the loosening force cannot be related directly to the force values seen *in vivo*. However, designs with lower loosening forces will show higher loosening rates *in vivo*. Han et al¹² showed that, in the specific case of a cemented NexGen high-flex design implanted in an Asian population performing daily weight-bearing high-flexion activities, the loosening rate was 38% at a mean of 32 months after operation. A similar loosening rate has been reported elsewhere for the cementless version of this implant.³³

In summary, our study has demonstrated that high-flexion designs have a greater risk for loosening of the femoral component than conventional TKR designs. The absence of femoral load sharing between the prosthetic component and the condylar bone during flexion is in our opinion an important contributing factor. The internal geometry of the femoral component and the presence of pegs play an important role in enhancing the fixation of high-flexion components.

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